

REMARKS/ARGUMENTS

In the Election/Restriction requirement dated October 2, 2008, the Examiner delineated the following inventions as being patentably distinct.

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| Group I, | Claims 1, 4-5, drawn to an aqueous solution preparation containing 7-ethyl-10-piperidinopiperdinocarbonyl-oxycamptothecin; and |
| Group II | Claims 2, 4-5, drawn to an aqueous solution preparation containing 7-ethyl-10-piperidinopiperdinocarbonyl-oxycamptothecin wherein the preparation further comprises cyclodextrin, ascorbic acid and sodium ascorbate, propylene glycol or at least one compound. |

The Examiner further required the election of a single species used in the preparation of an aqueous solution containing camptothecins. Accordingly, Applicants elect sodium sulfite (Na_2SO_3) found in Examples 3 and 4 and [0046] of the present application.

The claims of Groups I and II are integrally linked as a set-subset. Every element of Group I is contained in Group II, hence the dependency of Claim 2 in Claim 1. A dependent claim is one which contains all the features of another claim and is in the same category of claims as other claims. It does not matter if a dependent claim itself contains a further invention. All of the claims should be grouped together since they form a single general inventive concept.

Restriction is only proper if the claims of the restricted groups are either independent or patentably distinct and there would be a serious burden placed on the Examiner if restriction is not required (M.P.E.P. § 803). The burden of proof is on the Examiner to provide reasons and/or examples of support any conclusions in regard to patentable distinction (M.P.E.P. § 803). Moreover, when making a lack of unity of an invention in a national stage application, the Examiner has the burden of explaining why each group lacks unity with each other (i.e., why there is no single inventive concept specifically describing

the unique technical feature in each group) (M.P.E.P. § 1893.02(d)). It is a technical relationship that involves the same features, and it is this technical relationship that defines the contribution which each of the groups, taken as a whole, makes over the prior art.

In chemical cases, a specified group of materials which do not necessarily belong to an otherwise class can be claimed as a Markush group. The Markush practice sanctions the claiming together operable substances which could not be defined by generic language but which nevertheless have a community of chemical or physical characteristics. The members of the Markush group need only possess at least one property in common which is responsible for the chemical relationship. The same utility in a generic sense suffices.

The Examiner asserts that groups I-II do not relate to a single general inventive concept under PCT 13.1 and 13.2 because they lack the same corresponding technical feature.

The Examiner, however, has not considered that the claims in each group are considered related inventions under 37 C.F.R. § 1.475(b) in which the inventions are considered to have unity of invention. Applicants submit that while PCT Rules 13.1 and 13.2 are applicable, 37 C.F.R. § 1.475(b) provides in relevant part, that a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn to a product, process and use of said product.

Moreover, Applicants respectfully submit that a search of all the claims would not impose a serious burden on the Office. As the Office has not shown any evidence that a restriction should now be required when the International Report did not, restriction is now believed to be improper.

For the reasons set forth above, Applicants request that the restriction requirement be withdrawn.


Applicants request that if the invention of Group I is found allowable, withdrawn Group II, which includes the limitation of the allowable claims be required.

Applicants also request that should the elected species be found allowable, the Examiner expand the search to include the non-elected species.

Applicants submit that the above-identified application is now in condition for examination on the merits, and an early notice of such action is earnestly solicited.

Respectfully submitted,

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